John E. Flaherty
Ravin Patel
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc.

Ricardo Rodriguez
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000

Of Counsel for Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc.

Stephen M. Hash
BAKER BOTTS LLP
98 San Jacinto Blvd., Suite 1500
Austin, TX 78701-4078
(512) 322-2500

Of Counsel for Plaintiff Pozen Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC.,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL., INC., ACTAVIS PHARMA, INC., and ACTAVIS, INC.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis, Inc. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, "Horizon") are corporations operating and existing under the laws of the State of Delaware, with their principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.

2. Plaintiff Pozen Inc. ("Pozen") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1122 Oberlin Road, Raleigh, NC 27605-1137.

3. On information and belief, Defendant Actavis Laboratories FL, Inc. ("Actavis Laboratories") was formerly known as Watson Laboratories, Inc. – Florida, which was formerly known as Andrx Pharmaceuticals, Inc. ("Andrx Pharmaceuticals"). On information and belief, Actavis Laboratories is a corporation organized and existing under the laws of Florida, with its principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Actavis Laboratories is in the business of, *inter alia*, developing, manufacturing, marketing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

4. On information and belief, Defendant Actavis Pharma, Inc. ("Actavis Pharma") was formerly known as Watson Pharma, Inc. ("Watson Pharma"). On information and belief, Defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis Pharma is in the business of,

inter alia, selling and distributing generic copies of branded pharmaceutical products, including some that are manufactured by Actavis Laboratories and/or for which Actavis Laboratories is the named applicant of the approved ANDAs, throughout the United States, including within this district.

5. On information and belief, Defendant Actavis, Inc. ("Actavis") was formerly known as Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") until on or about January 24, 2013. On information and belief, Actavis is a corporation organized and existing under the laws of Nevada, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this district, through its own actions and through the actions of its agents and subsidiaries, including at least Actavis Laboratories and Actavis Pharma.

6. On information and belief, Watson Pharmaceuticals acquired Andrx Pharmaceuticals on or about November 3, 2006. On information and belief, Watson Pharmaceuticals renamed Andrx Pharmaceuticals as Watson Laboratories. On information and belief, Watson Laboratories was renamed as Actavis Laboratories.

7. On information and belief, Actavis Laboratories is a wholly-owned subsidiary of Andrx Corporation, a Delaware corporation, with its principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Andrx Corporation is a wholly-owned subsidiary of Actavis.

8. On information and belief, Actavis Pharma, formerly known as Watson Pharma, is another wholly-owned subsidiary of Actavis.

9. On information and belief, Actavis organizes its operations by divisions—including at least Generics, Brands, and Distribution—and, before the name change, Watson Pharmaceuticals reported its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. On information and belief, Watson Pharmaceuticals consolidated its financial results with subsidiaries in its SEC filings at least since 2007 and did not file separate financial reports to the SEC for each subsidiary.

10. On information and belief, Actavis' Generics Division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, Defendants act as agents of each other and/or work in concert with each other as integrated parts of the Generics Division. On information and belief, the Generics Division develops and submits Abbreviated New Drug Applications ("ANDAs") to the FDA, relying on contributions from at least Defendants.

11. On information and belief, the head of the Generics Division is an employee of Actavis, the Generic Division's ANDAs are submitted by at least Actavis Laboratories, the Generic Division's products are developed and manufactured by at least Actavis Laboratories, and the Generic Division's products are marketed, sold, and distributed throughout the United States, including in this district, by at least Actavis Pharma. On information and belief, Actavis Laboratories and Actavis Pharma are parties to one or more contractual agreements regarding the distribution of generic pharmaceutical products.

12. On information and belief, Defendants share with each other at least some common employees, officers, and directors.

13. On information and belief, Actavis Laboratories and Actavis Pharma are within the control of Actavis for purposes of responding to discovery in this action.

BACKGROUND

The NDA

14. Horizon Pharma, Inc. is the holder of New Drug Application ("NDA") No. 022511 for VIMOVO® (naproxen and esomeprazole magnesium) Delayed-Release Tablets, in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

15. VIMOVO® Delayed-Release Tablets are prescription drugs approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO® Delayed-Release Tablets.

The Patents-in-Suit

16. United States Patent No. 8,945,621 ("the '621 patent"), entitled "Method for Treating a Patient at Risk for Developing an NSAID-Associated Ulcer," was duly and legally issued by the United States Patent and Trademark Office on February 3, 2015. A true and correct copy of the '621 patent is attached as Exhibit A.

17. Horizon Pharma USA, Inc. and Pozen own the rights to the '621 patent. Horizon Pharma USA, Inc. is the exclusive licensee of Pozen's rights to the '621 patent. The '621 patent will expire on October 17, 2031.

18. The '621 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

19. United States Patent No. 9,220,698 ("the '698 patent"), entitled "Method for Delivering a Pharmaceutical Composition to Patient in Need Thereof," was duly and legally

issued by the United States Patent and Trademark Office on December 29, 2015. A true and correct copy of the '698 patent is attached as Exhibit B.

20. Horizon Pharma USA, Inc. and Pozen own the rights to the '698 patent. Horizon Pharma USA, Inc. is the exclusive licensee of Pozen's rights to the '698 patent. The '698 patent will expire on March 10, 2031.

21. The '698 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

22. United States Patent No. 9,345,695 ("the '695 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on May 24, 2016. A true and correct copy of the '695 patent is attached as Exhibit C.

23. Pozen owns the rights to the '695 patent. Horizon Pharma USA, Inc. is the exclusive licensee of the '695 patent. The '695 patent will expire on May 31, 2022.

24. The '695 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

The ANDA

25. On information and belief, Defendants filed ANDA No. 204470 ("Defendants' ANDA") with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and sale in the United States of naproxen and esomeprazole magnesium delayed-release tablets containing 375 mg or 500 mg of naproxen and 20.71 mg esomeprazole magnesium ("Actavis's ANDA Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

JURISDICTION AND VENUE

26. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

27. On information and belief, Defendants have been and are engaging in activities directed toward infringement of the '621, '698, and '695 patents (collectively, the "patents-in-suit") by, *inter alia*, submitting to the FDA ANDA No. 204470 and continuing to seek approval for Actavis' ANDA Product.

28. There is an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the patents-in-suit.

29. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, on information and belief, have purposely availed themselves of the benefits and protections of the laws of New Jersey such that they should reasonably anticipate being haled into court here; Defendants have had continuous and systematic contacts with this judicial district, including, on information and belief, maintaining executive offices in New Jersey and deriving substantial revenues from the sale of pharmaceutical products in New Jersey; and at least Actavis Pharma and Actavis, on information and belief, are licensed to do business within New Jersey. Thus, Defendants are subject to general jurisdiction in New Jersey.

30. On information and belief, Actavis Laboratories has previously purposefully availed itself of the benefits and protections of this district including, *inter alia*, by filing a complaint in the U.S. District Court for the District of New Jersey (S*hionogi Inc. et al. v. Nostrum Labs., Inc. et al.*, C.A. No. 1:12-cv-04402-RBK-JS (D.I. 1)) and asserting counterclaims in this Court (in *Depomed, Inc. v. Actavis Elizabeth LLC et al*., C.A. No. 3:12-cv-01358-JAP-

TJB (D.I. 47) and in *AstraZeneca AB et al. v. Actavis Laboratories FL Inc. et al*., C.A. No. 3:13-cv-03038-JAP-DEA (D.I. 54)).

31. On information and belief, the acts of Actavis Laboratories complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Actavis Pharma and Actavis.

32. On information and belief, Defendants acted in concert to develop Actavis' ANDA Product and to seek approval from the FDA to sell Actavis' ANDA Product throughout the United States, including within this judicial district.

33. On information and belief, Actavis Laboratories, Actavis Pharma, and Actavis participated in the preparation and/or filing of ANDA No 204470.

34. On information and belief, the FDA received ANDA No. 204470 from Defendants.

35. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 204470, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

36. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

COUNT I

(INFRINGEMENT OF THE '621 PATENT UNDER 35 U.S.C. § 271(e)(2))

37. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

38. The ’621 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, importation, offer for sale, or sale of the VIMOVO® product.

39. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the ’621 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA’s Orange Book.

40. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”) requires, inter alia, certification by the ANDA applicant that the subject patent in the Orange Book, here the ’621 patent, “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, inter alia, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.”

41. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

42. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The ’621 patent has an expiration date of October 17, 2031. Therefore, on

further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204470 before the '621 patent expires.

43. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis's ANDA Product infringes the '621 patent.

44. Defendants have infringed, either literally or under the doctrine of equivalents, the '621 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204470 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '621 patent before the expiration of the '621 patent.

45. On information and belief, Actavis's ANDA Product is a material for use in practicing the methods patented in the '621 patent, constitutes a material part of the inventions of the '621 patent, is especially made or especially adapted for use in an infringement of the '621 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis's ANDA Product is so made or so adapted. On information and belief, Defendants are aware that Actavis's ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '621 patent.

46. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '621 patent under 35 U.S.C. § 271(e)(2).

47. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II

(DECLARATORY JUDGMENT AS TO THE '621 PATENT)

48. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

49. The '621 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, importation, offer for sale, or sale of the VIMOVO® product.

50. On information and belief, Actavis's ANDA Product is a material for use in practicing the methods patented in the '621 patent, constitutes a material part of the inventions of the '621 patent, is especially made or especially adapted for use in an infringement of the '621 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis's ANDA Product is so made or so adapted.

51. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis's ANDA Product before the expiration of the '621 patent constitutes infringement of the '621 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

52. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, inter alia, FDA final approval to market Actavis's ANDA Product before February 28, 2023.

53. On information and belief, Defendants' intend to market Actavis's ANDA Product before the '621 patent expires on October 17, 2031.

54. On information and belief, Defendants continue to seek FDA final approval for Actavis's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, offer for sale, or sale in the United States or the importation into the United States of Actavis's ANDA Product, if approved, will infringe the '621 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

55. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, offer for sale, or sell in the United States or import into the United States Actavis's ANDA Product before the '621 patent expires.

56. On information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, or sale in the United States or importation into the United States of Actavis's ANDA Product after receiving FDA final approval of ANDA No. 204470 and before the '621 patent expires.

57. There is a definite and concrete, real and substantial, justiciable case or controversy between Plaintiffs and Defendants concerning infringement of the '621 patent by their ANDA Product such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by the Court.

58. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

59. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of Actavis's ANDA Product will infringe one or more claims of the '621 patent.

COUNT III

(INFRINGEMENT OF THE '698 PATENT UNDER 35 U.S.C. § 271(e)(2))

60. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

61. The '698 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, importation, offer for sale, or sale of the VIMOVO® product.

62. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the '698 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA's Orange Book.

63. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '698 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

64. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

65. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, inter alia, FDA final approval prior to February 28, 2023. The '698 patent has an expiration date of March 10, 2031. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204470 before the '698 patent expires.

66. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis' ANDA Product infringes the '698 patent.

67. Defendants have infringed, either literally or under the doctrine of equivalents, the '698 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204470 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '698 patent before the expiration of the '698 patent.

68. On information and belief, Actavis' ANDA Product contains the pharmaceutical composition patented in the '698 patent, is a material for use in practicing the methods patented in the '698 patent, constitutes a material part of the inventions of the '698 patent, is especially made or especially adapted for use in an infringement of the '698 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis' ANDA Product is so made or so adapted. On information and belief, Defendants are aware that Actavis' ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '698 patent.

69. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '698 patent under 35 U.S.C. § 271(e)(2).

70. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV

(DECLARATORY JUDGMENT AS TO THE '698 PATENT)

71. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

72. The '698 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, importation, offer for sale, or sale of the VIMOVO® product.

73. On information and belief, Actavis' ANDA Product contains the pharmaceutical composition patented in the '698 patent, is a material for use in practicing the methods patented in the '698 patent, constitutes a material part of the inventions of the '698 patent, is especially made or especially adapted for use in an infringement of the '698 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis' ANDA Product is so made or so adapted.

74. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis' ANDA Product before the expiration of the '698 patent constitutes infringement of the '698 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

75. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, *inter alia*, FDA final approval to market Actavis' ANDA Product before February 28, 2023.

76. On information and belief, Defendants' intend to market Actavis' ANDA Product before the '698 patent expires on March 10, 2031.

77. On information and belief, Defendants continue to seek FDA final approval for Actavis's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, offer for sale, or sale in the United States or the importation into the United States of Actavis's ANDA Product, if approved, will infringe the '698 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

78. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, offer for sale, or sell in the United States or import into the United States Actavis's ANDA Product before the '698 patent expires.

79. On information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, or sale in the United States or importation into the United States of Actavis's ANDA Product after receiving FDA final approval of ANDA No. 204470 and before the '698 patent expires.

80. There is a definite and concrete, real and substantial, justiciable case or controversy between Plaintiffs and Defendants concerning infringement of the '698 patent by their ANDA Product such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by the Court.

81. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

82. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of Actavis' ANDA Product will infringe one or more claims of the '698 patent.

COUNT V

(INFRINGEMENT OF THE '695 PATENT UNDER 35 U.S.C. § 271(e)(2))

83. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

84. The '695 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, import, offer for sale, or sale of the VIMOVO® product.

85. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the '695 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA's Orange Book.

86. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '695 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must

include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

87. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

88. On information and belief, Defendants are currently pursuing FDA final approval of their ANDA before the '695 patent expires. Defendants filed a Paragraph IV certification against the '695 patent on July 22, 2016.

89. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product infringes the '695 patent.

90. Defendants have infringed, either literally or under the doctrine of equivalents, the '695 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204470 and continuing to seek approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, or sale of a drug to be used as claimed in the '695 patent before the expiration of the '695 patent.

91. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '695 patent, constitutes a material part of the inventions of the '695 patent, is especially made or especially adapted for use in an infringement of the '695 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that their ANDA Product is

so made or so adapted. On information and belief, Defendants are aware that their ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '695 patent.

92. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '695 patent under 35 U.S.C. § 271(e)(2).

93. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT VI

(DECLARATORY JUDGMENT AS TO THE '695 PATENT)

94. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

95. The '695 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, importation, offer for sale, or sale of the VIMOVO® product.

96. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '695 patent, constitutes a material part of the inventions of the '695 patent, is especially made or especially adapted for use in an infringement of the '695 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that their ANDA Product is so made or so adapted.

97. On information and belief, the making, using, offering for sale, or selling in the United States or the importation into the United States of Defendants' ANDA Product before the

expiration of the '695 patent constitutes infringement of the '695 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

98. On information and belief, Defendants are seeking FDA final approval to market their ANDA Product before May 31, 2022.

99. On information and belief, Defendants continue to seek FDA final approval for their ANDA Product. On information and belief, Defendants are aware that the manufacture, use, offer for sale, or sale in the United States or the importation into the United States of their ANDA Product, if approved, will infringe the '695 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

100. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, offer for sale, or sell in the United States or import into the United States their ANDA Product before the '695 patent expires.

101. On information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, or sale in the United States or importation into the United States of their ANDA Product after receiving FDA final approval of ANDA No. 204470 and before the '695 patent expires.

102. There is a definite and concrete, real and substantial, justiciable case or controversy between Plaintiffs and Defendants concerning infringement of the '695 patent by their ANDA Product such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by the Court.

103. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

104. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of their ANDA Product will infringe one or more claims of the '695 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the submission of ANDA No. 204470 by Defendants infringes one or more claims of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A);

B. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 204470 shall be no earlier than the expiration date of the patents-in-suit patents or any later exclusivity to which Plaintiffs are or become entitled;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204470 no earlier than the expiration date of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

D. A declaration that Defendants have infringed the patents-in-suit;

E. A declaration that the commercial use, sale, offer for sale, manufacture in the United States and/or importation into the United States by Defendants of the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204470 would infringe

the patents-in-suit;

F. An order preliminarily and permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204470 no earlier than the expiration date of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

G. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such further and other relief as this Court may deem just and proper.

Dated: August 11, 2016

Respectfully submitted,

By: s/ John E. Flaherty

John E. Flaherty
Ravin Patel
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc.

Stephen M. Hash
BAKER BOTTS LLP
98 San Jacinto Blvd., Suite 1500
Austin, TX 78701-4078
(512) 322-2500

Of Counsel for Plaintiff Pozen Inc.

Ricardo Rodriguez
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000

Of Counsel for Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABS. INC., et al., C.A. No. 3:11-cv-02317-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABS. INC. et al, C.A. No. 3:13-cv-00091-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. LUPIN LTD., et al., C.A. No. 3:11-cv-04275-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC., et al., C.A. No. 3:13-cv-03038-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-04022-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC., et al, C.A. No. 3:15-cv-03322-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABORATORIES INC., et al, C.A. No. 3:15-cv-03324-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al v. LUPIN LTD., et al., C.A. No. 3:15-cv-03326-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. MYLAN PHARMACEUTICALS INC., et al., C.A. No. 3:15-cv-03327-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC. et al, C.A. No. 3:15-cv-08523-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC., et al., C.A. No. 3:15-cv-08524-MLC-DEA (D.N.J.); and

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC.,et al., C.A. No. 3:16-cv-00426-MLC-DEA (D.N.J.)

The foregoing cases involve products that contain esomeprazole magnesium and naproxen. The matter in controversy involves the same esomeprazole magnesium and naproxen formulations. All of these cases have been assigned to Hon. Mary L. Cooper, U.S.D.J. The Dr. Reddy's, Lupin, Actavis, and Mylan Pharmaceuticals cases have been consolidated for discovery purposes and have been assigned to Magistrate Judge Arpert.

Therefore, for the sake of judicial economy and with regard to Judge Cooper's and Judge Arpert's familiarity of the patents asserted in the matter in controversy, Plaintiffs believe these cases and the matter in controversy are all related. Accordingly, Plaintiffs respectfully request that the matter in controversy be assigned to Judge Cooper and Magistrate Judge Arpert.

Dated: August 11, 2016

Respectfully submitted,

By: s/ John E. Flaherty

John E. Flaherty
Ravin Patel
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc.

Stephen M. Hash
BAKER BOTTS LLP
98 San Jacinto Blvd., Suite 1500
Austin, TX 78701-4078
(512) 322-2500

Of Counsel for Plaintiff Pozen Inc.

Ricardo Rodriguez
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000

Of Counsel for Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc.